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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,534	05/31/2000	BARBARA ENSOLI	11340-003-999	9400

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JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER
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STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/555,534

Applicant(s)

ENSOLI, BARBARA

Examiner

Jeffrey Stucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 62,63,65,66,68,69,76,77,79 and 89-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62,63,65,66,68,69,76,77,79 and 89-141 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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This Office Action is in response to the amendment filed 25 April 2005. Claims 62, 63, 65, 66, 68, 69, 76, 77, 79, and 89-139 and new claims 140 and 141 are pending. Claims 62, 63, 65, 66, 68, 69, 76, 77, 79, and 89-123, 127-129, 133, and 135-141 are examined and rejected.

The rejection of claims 62, 63, 69, 77, 90, 91, and 96 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 115, 120, 128, 129, 133, 137, and new claims 140 and 141 under 35 U.S.C. § 102(b) as being anticipated by Chang et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest each and every element of amended claims 62 and 76 and, thus, their dependent claims. In particular, Chang allegedly does not teach or suggest a biologically active Tat protein in a form suitable for administration to a human because

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the eluted Tat protein in 2M NaCl would not be suitable for administration to a human and that the section cited by the Examiner disclosing raising rabbit polyclonal anti-Tat antibodies is for raising antibodies in rabbits. Applicant asserts that antigens administered to rabbits and mice for producing polyclonal antibodies are often combined with substances that cannot be administered to a human. Accordingly, Chang's disclosure of administering the Tat protein to rabbits in no way teaches the presently claimed biologically active Tat protein formulated for administration to a human. As such, Chang also does not anticipate the rejected or new claims.

Applicant argues that antigen injected into rabbits is not convincing because "in a form suitable for administration to a human" is an intended use. One can read "suitable" to mean a composition that will not kill the human recipient. This limitation does not put a specific structural limitation on the composition. Thus, the claimed invention is anticipated by Chang et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 112, 115, 120, 128, 129, 133, and 137 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Chengalvala et al. (Vaccine, 1999) is withdrawn in view of

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applicant's correct observation that the instant priority date antedates the Chengalvala et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 113-115, 118-120, 128, 129, 133, and 135-137 and new claims 140 and 141 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Heiman et al. (*Nature Med. Vac. Supp.*, 1998) is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claims 62 and 76 and Heiman does not cure the alleged deficiency of Chang. While Heiman discloses a number of recent research findings that influence HIV vaccine design, Heiman does not teach or suggest a Tat protein, much less teach or suggest a biologically active Tat protein in a form suitable for administration to a human. Heiman et al. was not cited to teach a Tat protein but to teach that numerous combinations of HIV proteins are known in the art, including, specifically, gag. Thus, the instantly claimed invention is obvious over Chang et al. in view of Heiman et al.

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The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-95, 97, 101-111, 115-117, 120-122, 128, 129, 133, 137-139, and new claims 140 and 141 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Vogel et al. (1995) is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that there is no teaching or suggestion in Chang of a biologically active Tat protein in a form suitable for administration to humans as recited in amended claims 62 and 76. Vogel does not cure the deficiency of Chang because Vogel does not teach or suggest a Tat protein. Instead, Vogel discloses a wide variety of organic and inorganic compounds that are useful for improving the immunogenicity of vaccines and lacks a reasonable expectation of success of the claimed invention.

Vogel et al. was not cited to teach Tat but to teach various antigen enhancing compounds. As Applicant notes, Vogel et al. is a compendium of adjuvants which teaches a wide variety of compounds which are "useful for improving the immunogenicity of vaccines". Applicant does not specifically indicate why widely effective immune modulators suitable for a wide range of antigens would not work with Tat as was asserted in the previous

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Office Action. Thus, the instantly claimed invention is obvious over Chang et al. in view of Vogel et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 115, 120, 123, 128, 129, 133, and 137 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Hengge et al. (AIDS, 1998) is withdrawn in view of Applicant's evidence that Hengge et al. is not available as prior art.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 99, 106, 107, 115, 120, 128, 129, 133, 137, and new claims 104 and 141 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Castignolles et al. (Vaccine, 1996) is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues there is no suggestion of the claimed invention in the combined teachings of the references because there is no teaching or suggestion in Chang of a biologically active Tat protein in a form suitable for administration to a human as recited in amended claims 62 and 76. Castignolles does not cure the alleged deficiency of Chang because Castignolles does not teach or suggest a Tat protein because it discloses a new family of biovectors that are

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useful for enhancing the immunogenicity of rabies antigens and supposedly lacks a reasonable expectation of success.

Castignolles et al. was not cited to teach Tat but to teach that nanoparticles have immunostimulating properties. As Applicant notes, Castignolles et al. teaches a family of biovectors that are useful for enhancing the immunogenicity of antigens. Applicant does not specifically indicate why effective immune modulators suitable for antigens would not work with Tat as was asserted in the previous Office Action. Thus, the instantly claimed invention is obvious over Chang et al. in view of Castignolles et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 100, 106, 107, 115, 120, 128, 129, 133, 137, and new claims 140 and 141 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Ramshaw et al. (*J. of imm. methods*, 1977) is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues there is no suggestion of the claimed invention in the combined teachings of the references. As discussed above, there is no teaching or suggestion in Chang of a biologically active Tat protein in a form suitable for administration to a human as recited in



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amended claims 62 and 76. Ramshaw does not cure the alleged deficiency of Chang because Ramshaw does not teach or suggest a Tat protein because it discloses that, on a dose basis, antigen coupled to autologous red blood cells is 1,000 to 10,000-fold more efficient at inducing an antibody response than the soluble form and allegedly lacks a reasonable expectation of success.

Ramshaw et al. was not cited to teach Tat but to teach that autologous erythrocytes are efficient at inducing an immune response. Applicant does not specifically indicate why erythrocytes would not work with Tat as was asserted in the previous Office Action. Thus, the instant invention is obvious over Chang et al. in view of Ramshaw et al.

The following are new grounds of rejection:

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 112, 115, 120, 128, 129, 133, and 137 are rejected under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Livingston et al. (*J. of Immunol.*, Aug. 1997).

The claimed invention is further limited to conjugating a T-helper universal epitope of tetanus toxoid to the Tat protein.

The relevance of Chang et al. has been previously set forth.

Livingston et al. teach that conjugating the T helper epitope of tetanus toxoid to HBsAg enhances the immunogenicity of the HBsAg. See the entire reference. Note that the reference teaches on the first page, second column that the T helper epitope of tetanus toxoid is a universal HTL epitope which greatly potentiates the CTL responses elicited by a vaccine. It would have been obvious to one of ordinary skill in the art at the time the invention was made to conjugate the T cell helper epitope of tetanus toxin of Livingston et al. to the Tat protein of Chang et al. One would be motivated to do this in order to enhance the immunogenicity Chang et al.'s Tat protein. Thus, the instant invention is obvious over Chang et al. in view of Livingston et al.

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Claims 62, 63, 65, 66, 68, 69, 76, 77, 79, 89, 90, 93-94, 106, 107, 115, 120, 123, 128, 129, 133, and 137 are rejected under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Barry et al. (*Clin. Pharmacokinetics*, Mar 1997).

The invention is further limited to the addition of an inhibitor of viral replication to the claimed composition.

The relevance of Chang et al. has been previously set forth.

Barry et al. teach that various viral inhibitor compounds were known in the art. See the entire reference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the addition of an antiviral composition in the composition to inhibit viral disease. Thus, the instantly claimed invention is obvious over Chang et al. in view of Barry et al.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.

  
JEFFREY STUCKER  
PRIMARY EXAMINER